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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/798,198  | 03/10/2004  | Michael J. Munchhof  | PC23318A            | 6197             |
| 28523   | 7590        | 02/06/2006           | EXAMINER            |                  |
| PFIZER INC.<br>PATENT DEPARTMENT, MS8260-1611<br>EASTERN POINT ROAD<br>GROTON, CT 06340 |             |                      | TUCKER, ZACHARY C   |                  |
|   |             | ART UNIT             | PAPER NUMBER        |                  |
|   |             |                      | 1624                |                  |

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                      |  |
|------------------------------|------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 10/798,198             | MUNCHHOF, MICHAEL J. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |  |
|                              | Zachary C. Tucker      | 1624                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 10May,18Jun04.

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

***Requirement for Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to chemical compounds of formulae (I), (II) and (III), classified in class/subclasses 544/405 (when the 2-position of pyrazine ring is "Het") and 544/406 (when the 2-position of pyrazine ring is phenyl or "Ar").
- II. Claims 12-14, drawn to a pharmaceutical composition comprising a compound as set forth in Group I hereinabove, and a method of treating or preventing a TGF-related disease state in a mammal, classified in class/subclass 514/255.05 (when the 2-position of pyrazine ring is "Het") and 514/255.06 (when 2-position of pyrazine ring is phenyl or "Ar").

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case both conditions (1) and (2) apply.

Compounds as set forth in Group I are not limited in their utility only to active ingredients in pharmaceutical compositions or as therapeutic agents; such compounds are known from the prior art to be useful as intermediates in chemical syntheses, such as for making pteridinone compounds. De Meester et al, *Journal of Heterocyclic*

*Chemistry*, vol. 24, pages 1109-1116 (1989) – cited in the Information Disclosure Statement filed 18 June 2004 – discloses a compound from Group I as set forth hereinabove, as such an intermediate (page 1110, compounds 4). Conversely, methods in Group II can be practiced with materially different products such as ciprofloxacin for the treatment of acute glomerulonephritis caused by renal *E. coli* infection, or antihyperglycemic and antihypertensive drugs for the treatment of diabetic nephropathy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, also as shown by the different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Abstract of the Disclosure***

The specification is objected to because the abstract of the disclosure does not convey a concise description of the claimed invention. When the invention is a family of novel chemical compounds, at least a generic structural formula should appear in the abstract.

“Pyrazine compounds,” the sole chemical descriptor of the compounds of the invention which is referenced in the abstract, is no more descriptive of the invention

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than the title of the application. It is commended to applicants that the three generic structures – those of formulae (I), (II) and (III) – be introduced into the abstract.

See MPEP § 608.01(b).

***Conclusion***

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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